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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,095	03/06/2002	Brian Bates	8627-051	8504

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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,095

Applicant(s)

BATES, BRIAN

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-4,7,9,11-13, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,036,725 to Avellanet.

Avellanet discloses a stent in Figure 1 that includes a single wire support frame (30). Members (16) are disposed about a portion of the circumference. Avellanet explains that portions (16) can include a layer of graft material, such as PTFE (column 6, lines 50-60). This is considered to meet the broad limitation of *"graft material disposed on a portion of the support frame."* The stent can engage the entire inner circumference of a vessel. The graft material (16) extends only a portion of the length of the frame and about ½ the circumference. The device can be deployed with a balloon catheter (Fig. 22) and with a retractable sheath (44).

Regarding the limitation "formed from a pattern in a sheet" in claims 7 and 21, this is only a product by process recitation. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Therefore, the limitation was not given patentable weight.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1 - 8,10-13,18,19,21,22,24, 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,191 to Summers in view of US Patent No. 6,231,597 to Deem et al.

Summers discloses several stent patterns in Figures 1-5 and 21 that meet many limitations of the claims. The embodiment of the stent in Figures 1-5 is formed from a single wire (column 3, line 65), has ring segments joined by curved regions, and adjacent rings are interleaved. The embodiment in Figure 21 has a longitudinal support. Summers fails to include a partial circumference graft with the stent frame.

Deem discloses a stent-graft in Figure 1, wherein the support frame (14) of the stent is formed from a single wire. Deem teaches that a single wire stent can include a partial circumference graft (102) attached to it (Figure 4). The partial circumference graft is particularly useful in spanning an abnormality to promote clotting and endothelial growth, while preventing resistance to blood flow (column 5, line 20). The graft material (102) extends over approximately half the circumference of the stent. Since the basic stent frames of Deem and Summers are so similar, one would have been motivated to combine the teachings of Deem with Summers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispose a partial circumference graft on the stent of Summers, as Deem teaches that this provides protection to an abnormality with less resistance to blood flow. Applicant provides support in the specification that it is a matter of design choice to use a full circumference stent instead of a C-shaped stent [0027], as disclosed by Deem, with the partial circumference graft material.

Regarding claims 14,20, and 23: The partial circumference graft extends half the circumference of the frame instead of only one-fourth the circumference. It would have been an obvious matter of design choice to reduce the length of the graft around circumference of the frame, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

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3. Claims 15 – 17, 25 –27, and 36 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers in view of Deem, as explained above, and further in view of US Patent No. 6,464,720 to Boatman et al.

The modified Summers device includes all the limitations of the claims, except for three radiopaque markers adjacent to the edge of the graft material. The edge of the graft material is at the edge of the stent frame, so radiopaque markers at the edge of the stent frame would meet this limitation.

Boatman discloses a wire frame stent. Boatman teaches that it is particularly useful to have three radiopaque markers positioned at both the proximal and distal ends of the stent so that it can be clearly viewed to determine its exact location (column 19, lines 21-67). As shown in Figure 28, three radiopaque markers (102,103,104) are located at the edge of the stent frame. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include three radiopaque markers at the edge of the stent frame of the modified Summers device, as Boatman teaches that this arrangement of radiopaque markers aids in the determination of the exact location of the stent in the body.

Response to Arguments

4. Applicant argues that Avellanet does not meet the limitation of "graft material." This is a fairly broad limitation, which encompasses many materials, including those of Avellanet. Applicant did not choose to specify particular graft materials in the claims. In lines 50-61 of column 6, Avellanet explains that the foil members can include PTFE, a well know graft material. There are other well know graft materials listed here. Therefore, Avellanet does meet the requirement of "graft material."

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5. Applicant argues that the purposes between the foil members of Avellanet and the graft material of the claims are different. In response to this argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
1/7/05

SKW

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER